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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,924	10/31/2001	Shin-ichi Hashimoto	P21252	8540
7055	7590	10/06/2004	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			MARX, IRENE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/868,924	Applicant(s) HASHIMOTO ET AL.	
	Examiner Irene Marx	Art Unit 1651	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment. (See 37 CFR 1.116 and 41.33(a)).

4. ☒ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-9.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☒ Other: PTOL-324

Irene Marx

Irene Marx
 Primary Examiner
 Art Unit: 1651

Notice of Non-Compliant Amendment (37 CFR 1.121)

Application No.	Applicant(s)	
09/868,924	HASHIMOTO ET AL.	
Examiner	Art Unit	
Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 23 September 2004 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
 - ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
 - ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☐ 3. Amendments to the drawings: _____.
- ☒ 4. Amendments to the claims:
 - ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims).
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☒ E. Other: amended material does not include markings in claims 1 and 3 and/or amendments are incorrect.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/officeflyer.pdf>.

PRELIMINARY AMENDMENT AND NON-FINAL AMENDMENT:

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given ONE MONTH, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and **this ONE MONTH time limit is not extendable.**

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), and since the amendment appears to be a *bona fide* attempt to be a complete reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH, or thirty (30) days, whichever is longer, from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a).**

Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted. 37 CFR 1.121(h).

AFTER-FINAL AMENDMENT:

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action Before the Filing of an Appeal Brief (PTOL-303). **The period for reply to a final rejection continues to run from the mailing date of the final Office action,** and is not affected by the non-compliant status of the amendment.

If applicant wishes to resubmit the after-final amendment, the ENTIRE corrected after-final amendment must be resubmitted within the time period set forth in the final Office action.

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The recitation of "*Gordonia*" in claim 7, line 7 is queried.

Note:

The proposed amendment raises new issues that would require further consideration and/or search with respect to the structures in claim 1, pages 8 and 10-11, wherein the designations of the figures are confusing and improper.

The information disclosure statement (IDS) submitted on 7/7/04 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement was considered by the examiner. It is recommended that a form 1449 be filed to assure that the documents are listed on any patent that matures from this application.

Applicant's arguments have been fully considered but they are not deemed to be persuasive. The arguments directed to the amended claims do not pertain to the claims under examination.

Counsel indicates that the Examiner has not adequately explained why the strains are not patentable. To begin with, it is noted that the strains *per se* are not claimed, but rather a process of making a product with a well known class of microorganisms. The process as claimed is not patentable in view of the references cited because each of the references discloses a process of hydroxylation using one or more strains of microorganisms having the required properties and which are closely related to the strains used in the instant invention as explained in the first Office action. Due to the pervasive reclassification of strains within the claim designated genera and species, claims directed to whole genera or whole species do not appear patentable, because they read on the references cited, and applicant has not demonstrated otherwise with objective evidence.

In response to the arguments directed to chemotaxonomical characteristics, it is uncertain how these arguments pertain to the broad invention as claimed. The claims are not limited to the recitation of *Rhodococcus* as extensively argued. The claims are directed to a microorganism or to any *Mycobacterium*, *Corynebacterium*, *Brevibacterium*, *Rhodococcus*, *Gordonia*, *Arthrobacter*, *Micrococcus*, *Cellulomonas* and *Sphingomonas* and various species thereof. Applicant has relied on a dendrogram constructed in 2001 to try to overcome the rejection. However, this dendrogram does not alter the inherent properties of the strains. In addition, the evidence presented is incomplete and defective in that the data from which the dendrogram is

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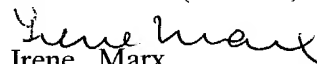
constructed is not presented. Thus its nexus with the invention as claimed cannot be readily assessed. Moreover, there is no clear indication on how the dendrogram overcomes the obviousness portion of the rejection. Even if the genera and species are not the same, they are closely related and the dendrogram does not show otherwise. Applicant has not specifically discussed how the dendrogram pertains to the claims as written. It is emphasized that the claims rejected are not specific as to the strains used. In addition, there is not clear indication of the availability to one of ordinary skill in the art of this dendrogram at the time the claimed invention was made.

As noted in the last Office action, claims directed to specific strains would be patentable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Irene Marx
Primary Examiner
Art Unit 1651